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EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT PAPER NUMBER

3736

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/707,022

Applicant(s)

MILLER ET AL.

Examiner

Charles A. Marmor, II

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-84 is/are pending in the application.
- 4a) Of the above claim(s) 2-15, 27, 29, 30, 32, 33, 39 and 46-84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 16, 18-24, 26, 31, 38 and 42-44 is/are rejected.
- 7) ☒ Claim(s) 17, 25, 28, 34-37, 40, 41 and 45 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 November 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 3736

DETAILED ACTION

1. This Office Action is responsive to the Response to Restriction Requirement filed March 10, 2003.

Election/Restrictions

2. Applicant's election without traverse of Invention I, claims 1, 12-49 and 69 in Paper No. 17 is acknowledged. Claims 12-15, 27, 29, 30, 32, 33, 39, 46-49 and 69 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 17.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

- a. It does not identify the citizenship of each inventor.
- b. It was not dated by inventor Charles Butcher.

Information Disclosure Statement

4. The reference entitled "Engineering News, Probe Reduces Breast Biopsy Trauma" cited as other prior art in the information disclosure statement filed November 6, 2000 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the publication date of the reference has not been disclosed. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e).
See MPEP § 609 ¶ C(1).

Drawings

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: "65" as illustrated in Fig. 3A. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

6. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed

Art Unit: 3736

150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

7. The abstract of the disclosure is objected to because it exceeds the 150 word limit.

Correction is required. See MPEP § 608.01(b).

8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

9. The disclosure is objected to because of the following informalities:

- a. On page 9, line 5, "of" apparently should be deleted.
- b. On page 10, line 2, "patient" apparently should read --patients--.
- c. The Brief Description of the Figures is objected to, particularly at page 15. A brief description, as set forth in 37 CFR 1.74, of Figure 11 has not been provided.
- d. On page 17, line 5, --a-- apparently should be inserted before "tube-within-a-tube".
- e. On page 22, line 1, "rotational" apparently should read --rotation--.
- f. On page 28, line 21, "conceals" apparently should read --conceal--.
- g. On page 31, line 8, "113" apparently should read --13--.
- h. On page 38, line 5, --line-- apparently should be inserted following "pressure".
- i. On page 41, line 13, "140" apparently should read --40--.

Art Unit: 3736

- j. On page 43, line 13, "195" apparently should read --185--.
 - k. On page 44, line 5, "184" apparently should read --194--.
 - l. On page 47, line 14, "66" apparently should read --63--.
 - m. On page 47, line 25, "indicators" apparently should read --indicator--.
 - n. In the sentence on page 50, lines 2-4, the element "reciprocating motor" conflicts with the reference sign designated to the part in said sentence and in Figure 11. Prior to this recitation, the "reciprocating motor" has been designated reference sign "22" while the "rotary motor" has been designated reference sign "20".
 - o. On page 51, line 5, --is-- apparently should be inserted before "manufactured".
- Appropriate correction is required.

10. The use of the trademark Inconel® has been noted in this application. Each letter of the mark should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

11. Claim 19 is objected to because of the following informalities: in line 1, "claim18" apparently should read --claim 18--. Appropriate correction is required.

Art Unit: 3736

12. Claim 24 is objected to because of the following informalities: in line 2, “the” apparently should read --a--. Appropriate correction is required.

13. Claim 34 is objected to because of the following informalities: in line 2, a hyphen apparently should be inserted between tissue and receiving. Appropriate correction is required.

14. Claim 35 is objected to because of the following informalities: in line 1, “claim1” apparently should read --claim 1--. Appropriate correction is required.

15. Claim 41 is objected to because of the following informalities: in line 1, --first hydraulic-- apparently should be inserted before “rotary” in order to maintain consistent terminology for the limitation in the claims. Appropriate correction is required.

16. Claim 42 is objected to because of the following informalities:

- a. In line 3, “connection” apparently should read --communication--.
- b. In lines 7 and 8, --hydraulic rotary-- apparently should be inserted before “motor” in order to maintain consistent terminology for the limitation in the claims.

Appropriate correction is required.

17. Claim 43 is objected to because of the following informalities: in line 1, --reciprocating-- apparently should be inserted before “motor” in order to maintain consistent terminology for the limitation in the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

18. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

19. Claims 42-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 recites the limitation "said hollow axle" in line 6. There is insufficient antecedent basis for this limitation in the claim. There is no "hollow axle" disclosed in the claims prior to this recitation. The limitation "said hollow axle" apparently should read --said tubular axle--.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. Claims 1, 24, 26, 31 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hibner et al. ('462) in view of Cucin ('973).

Hibner et al. teach an automated surgical biopsy device. The device includes an outer

Art Unit: 3736

cannula **70** defining a tissue-receiving opening **78** adjacent a distal end thereof; an inner cannula **96** slidably disposed within the outer cannula and having a lumen **95** and an open distal cutting end **97**; a first rotary motor **338** operably coupled to the inner cannula to rotate the inner cannula; and a second reciprocating motor **340** operably coupled to the inner cannula to translate the inner cannula within the outer cannula. A handpiece **43** supports the inner cannula and the motors. The handpiece is removably coupled to a collection trap **318** having a filter element disposed therein. A vacuum source **330** is provided to aspirate tissue through the inner lumen to the collection trap. A cover **252** is removeably engagable to the handpiece. Tangs **144** project from the inner surface of the cutter to be received in engagement notches on the handpiece. A vacuum lumen **76** along the length of the outer cannula is disposed diametrically opposite the tissue-receiving opening and forms a stiffening element that inherently increases the bending resistance of the outer cannula. Hibner et al. teach all of the limitations of the claims except that the motors are hydraulic motors that are connected by a hydraulic system to a source of pressurized fluid.

Cucin teaches that it is known in the surgical art that electrical and gas or compressed-air hydraulic motors are interchangeable for driving an inner cannula in a reciprocating or rotary manner with respect to an outer cannula. Cucin further teaches that a hydraulic system must be provided to connect the gas or compressed-air hydraulic motors to a source of pressurized fluid.

It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to use hydraulic motors similar to those of Cucin in place of the electric motors in a tissue cutting instrument similar to that of Hibner et al. as an engineering design

Art Unit: 3736

choice, merely substituting one type of motor for another that is capable of performing an equivalent function.

22. Claims 16 and 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hibner et al. ('462) in view of Cucin ('973) as applied to claim 1 above, and further in view of Ritchart et al. ('547). Hibner et al., as modified by Cucin, teach all of the limitations of the claims except that the cutting edge of the inner cannula is an inwardly beveled surface and that the outer cannula is removably engageable to the handpiece. Ritchart et al. teach a device for automated biopsy including an inner cannula **22** having an inwardly beveled cutting edge (Figs 5 and 6) and an outer cannula **20** that can be removably engaged with a handpiece (Fig. 1). It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to provide a tissue cutting device similar to that of Hibner et al., as modified by Cucin, with an inner cannula having an inwardly beveled cutting surface similar to that of Ritchart et al. in order to efficiently cut tissue extending through a tissue receiving opening in the outer cannula with minimal tearing of the tissue such that tissue damage is limited. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to provide a tissue cutting device similar to that of Hibner et al., as modified by Cucin, with an outer cannula that is removably engaged with the handpiece similar to that of Ritchart et al. in order to permit the outer cannula to be disposed of after use while the housing and driving elements can be retained for repeated use.

Allowable Subject Matter

23. Claims 17, 25, 28, 34-37, 40, 41 and 45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

24. Claims 42-44 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

25. The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 17 and 34, no prior art of record teach or suggest a tissue cutting device, as claimed by Applicant in claim 1, where a dimple is provided in the inner surface of the outer cannula, immediately proximal to the tissue receiving opening, that is sized to fit between the inner cannula and the outer cannula.

Regarding claims 25 and 28, no prior art of record teach or suggest a tissue cutting device, as claimed by Applicant in claim 24, where the stiffening element is a longitudinally extending rib defined in the outer surface of the outer cannula.

Regarding claims 35-37, no prior art of record teach or suggest a tissue cutting device, as claimed by Applicant in claim 1, where tissue receiving opening has teeth formed in the sides thereof arranged to engage tissue drawn into the opening.

Regarding claims 40-44, no prior art of record teach or suggest a tissue cutting

Art Unit: 3736

device, as claimed by Applicant in claim 1, where the hydraulic rotary motor is coupled to the inner cannula by a tubular axle and a coupler.

Regarding claim 45, no prior art of record teach or suggest a tissue cutting device, as claimed by Applicant in claim 1, where the hydraulic reciprocating motor includes a hydraulic cylinder having a piston and a return spring disposed therein.

Conclusion

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kaplan et al. ('701) teach a biopsy needle instrument that is driven by an electric or hydraulic motor.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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September 22, 2003